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UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

IN RE LIPOCINE INC. SECURITIES LITIGATION	**Civ. Action No.: 2:17-cv-00182-DB**
This Document Relates To: All Actions	**PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS**
	Judge Dee Benson

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PRELIMINARY STATEMENT

Anyone who has ever taken an FDA approved drug understands the importance of dosing. If you take too little, the drug is not effective; if you take too much, the drug is not safe. Therefore, before the FDA can approve a drug, the company seeking its approval must devise a dosing algorithm that is thoroughly vetted during clinical testing to assess efficacy and safety. The dosing algorithm includes a titration scheme, which is the process of gradually adjusting the dose of a medication until optimal results are reached. Lipocine, a small company with no FDA approved drugs on the market, conducted clinical testing of its lead drug candidate LPCN 1021, which included a particular titration scheme. That fact is not in dispute. There can also be no dispute that the titration protocol was a material element of the Lipocine testosterone drug trial. Indeed, the Company acknowledged as such in its Class Period SEC filings, wherein it described its titration scheme in detail, as well as in a corporate presentation at a Needham Healthcare Conference where Lipocine distinguished LPCN 1021 from competitor drugs based on the number of dose titrations required.

There is also no dispute, that when Defendants touted the efficacy and safety results from the LPCN 1021 clinical trial, they discussed those results in tandem with the description of the titration scheme tested. However, when the Company sought FDA approval to market the drug, they sought approval for an entirely different, *untested*, titration scheme for use in real world practice than what was tested during the clinical trials, a material fact which Defendants failed to disclose to investors. Submitting an application for FDA approval of LPCN 1021 with an untested titration scheme raised a serious risk that the FDA would issue a Complete Response Letter rejecting that application.

This bait and switch on the FDA, much less the investors, is inexplicable. Defendants have never provided any explanation, much less a compelling one, for why they sought approval

for a different titration scheme than the one tested in the clinical trials, if indeed the clinical trials results were as stellar as they represented. Far more troubling is Defendants' decision to hide that fact from investors who had a right to know the Company's lead drug candidate faced a real risk of FDA rejection. Indeed, the issues with the titration schemes were so problematic that, at the FDA's urging, the Company initiated *two additional clinical trials both of which use fixed dosing regimens without any titration scheme. See* Jacobsen Decl., Ex. G, page 6.

The scienter of Defendant CEO Patel and Defendant CFO Brown is undeniable. They stood at the helm of a small tight knit company with no approved drugs on the market, and only one viable candidate up for approval. They signed the SEC filings and gave presentations in which they put themselves forth as fully knowledgeable on the details of the LPCN 1021 development activities, the results of the Phase 3 trial including titration, efficacy, and safety, and the FDA regulatory approval process. That Defendants expended "vast sums" on the clinical trial is not exculpatory. Any argument that it is focuses on motive, which is not required in the Tenth Circuit to allege scienter. In any event, the trial had been completed, and the monies expended, before the decision was made to change the titration scheme in the NDA. Moreover, companies often "gamble" when making business decisions, such as the one the Defendants made here to submit the LPCN 1021 NDA with a different titration scheme. While taking a gamble may not amount to 10(b) liability, failing to inform investors of the gamble does.

With the misleading statement and scienter elements of the claim established, and the other elements of the claim conceded, Defendants' motion must fail.

STATEMENT OF FACTS[1]

LPCN 1021, branded as TLANDO, is an oral testosterone replacement therapy designed for twice a day dosing. It is also the lead product candidate for Lipocine, a small tight knit company which does not have any Food and Drug Administration approved drugs currently on the market. ¶ 2. Indeed, the only other two drugs in its portfolio during the Class Period were LPCN 1111 and LPCN 1107, both of which lagged far behind LPCN 1021 in the FDA regulatory approval process. ¶ 16. Defendant CEO Mahesh Patel ("Patel") and Defendant CFO Morgan R. Brown ("Brown") stood at the helm of Lipocine throughout the entire Class Period. During that timeframe, Lipocine only had between 17-25 employees, only half of whom were engaged in "drug development activities," while the rest engaged "in general, administration, marketing and sales functions." ¶ 17.

Without any FDA approved drugs on the market, Lipocine had to rely on funding its operations through the sale of equity securities and convertible debt and through up-front payments, research funding and milestone payments from its license and collaboration arrangements. The Company made clear throughout the Class Period that it did not expect to generate revenue from product sales until it obtained regulatory approval of LPCN 1021. ¶ 18.

The FDA Approval Process for LPCN 1021

Before the Company can market LPCN 1021 in the United States, it has to obtain FDA approval of the drug under a §505(b)(2) New Drug Application ("NDA"). ¶ 13.

The FDA requires rigorous scientific testing to ensure that a drug is safe and effective for its intended use before the FDA will permit it to be marketed in the United States. Before considering approval of a drug for its indicated use, the FDA requires a "sponsor" to submit a

[1] All ¶ __references are to the Amended Complaint for Violation of the Federal Securities Laws, filed on April 27, 2017 (Doc. No. 48)("Complaint").

NDA for consideration, which contains data from clinical trials, preclinical studies, and manufacturing information that supports the product's safety and efficacy. 21 U.S.C. 355(b); 21 CFR 314.50(d). ¶ 14. Clinical testing typically involves a three-phase process. The third and final phase, known as Phase 3, is a large scale, multicenter, well-controlled clinical trial conducted on patients with a specific disease to generate enough data to statistically evaluate the efficacy and safety of the product, as the FDA requires, to establish the overall benefit-risk relationship of the drug and to provide adequate information for labeling. INC Research administered the Phase 3 study and oversaw the clinical trial sites for Lipocine. ¶ 15. Phase 3 was referred to as the Study of Oral Androgen Replacement, or "SOAR," trial.

All subjects that were randomized to receive LPCN 1021 during the Phase 3 trial were initially started at 225 mg testosterone undecanoate (TU) twice daily, which is equivalent to approximately 142 mg of testosterone twice daily. If needed, the dose was titrated up to 300 mg TU twice daily or down to 150 mg TU twice daily, and was dependent on serum testosterone levels measured during week 3 and week 7. "Titration" is the process of gradually adjusting the dose of a medication until optimal results are reached. The aforementioned titration scheme for LPCN 1021 used during Phase 3 did not match the titration scheme for which Lipocine requested FDA approval per its NDA. In other words, any efficacy or safety information gleaned from the Phase 3 trial data did not take into account the way the drug would actually be used in real world practice. ¶ 16.

Nevertheless, while touting the Phase 3 clinical trial results for LPCN 1021 both in terms of efficacy and safety, Defendants failed to reveal that the trial results were based on a dosing scheme used for LPCN 1021 during the clinical trial ***that differed significantly*** from the dosing

scheme the Company proposed to use in real world clinical practice, as described in Lipocine's New Drug Application to the Food and Drug Administration. ¶ 2.

Materially False and Misleading Statements

On June 29, 2015, the Company issued a press release touting the safety and efficacy results of the SOAR Phase 3 trial for LPCN 1021. ***The press release described the titration scheme used for patients treated with LPCN 1021 during the Phase 3 trial***. ("All subjects randomized to LPCN 1021 were started at 225 mg testosterone undecanoate ("TU") (equivalent to ~ 142 mg of testosterone) twice daily ("BID") and then dose titrated, if needed, up to 300 mg TU BID or down to 150 mg TU BID. Dose titration decisions were based on serum testosterone levels measured during weeks 3 and 7.") The press release was false and misleading because the Company failed to disclose that the reported results from the Phase 3 clinical trial, including information regarding efficacy, safety, and serious adverse events ("SAEs"), related to a titration scheme that differed significantly from the titration scheme to be included in the NDA for submission to the FDA for clinical practice thus creating a substantial risk that the FDA would reject the LPCN 1021 NDA. ¶ 20.

On August 11, 2015, the Company filed a Form 10-Q with the SEC for the quarter ended June 30, 2015 ("2Q 2015 10-Q"), which was signed by Defendants Patel and Brown. The 2Q 2015 10-Q discussed the Phase 3 trial in detail, providing a comprehensive explanation of the safety and efficacy results. As part of that discussion, the 2Q 2015 10-Q also once again described the titration scheme, but failed to mention that it differed significantly from the proposed titration scheme for clinical practice. Defendants also discussed the status of the NDA approval process without revealing the deficiencies with the NDA, *i.e.*, the titration scheme discrepancy, which created a risk that the Company would ultimately receive a Complete Response Letter from the FDA. For example, the 10-Q revealed that the Company had its pre-

NDA meeting with the FDA, whose purpose was "to discuss and obtain concurrence regarding adequacy for submission of the proposed NDA package for LPCN 1021 and to receive guidance on the 505(b) (2) filing and approval." The Company assured the market that, "[***b***]***ased on the FDA's preliminary response, we do not expect to conduct any additional clinical studies other than the labeling "food effect" study which was completed in May 2015.***" Missing from this assurance was the fact that the Company had not told the FDA during this meeting that it planned to submit the NDA with a proposed titration scheme that different materially from that used during the Phase 3 trial—a change which would virtually guarantee a request from the FDA for ***additional clinical studies***. ¶ 22.

The same day, the Company issued a press release, which described an underwritten public offering of 5,347,500 shares of its common stock at $6.50 per share for gross proceeds of $34.8 million, which once again underscored its need for money to fund its operation until it obtained FDA approval for one of its drugs. ¶ 24. While raising this money, the Company did not disclose that prospects for its lead drug candidate were questionable given the divergent titration schemes between Phase 3 trial practice and intended real world clinical practice. ¶ 25

On August 31, 2015, the Company issued a press release announcing its submission of the LPCN 1021 NDA to the FDA, which claimed that the filing was "supported by results from Lipocine's Study of Oral Androgen Replacement ("SOAR") pivotal Phase 3 clinical study (http://clinicaltrials.gov/show/NCT02081300) evaluating efficacy and safety of LPCN 1021 in hypogonadal men with low testosterone." ¶ 26. Indeed, the press release went so far as to discuss dose titration without revealing that the Phase 3 clinical study results did not in fact support the NDA filing because it set forth a different titration scheme than used during the trial.

On October 29, 2015, the Company issued a press release announcing the FDA's acceptance of the Company's NDA for LPCN 1021. ¶ 28. That press release, as well as the third quarter 10-Q filed two weeks later, once again omitted any mention of its deficiencies. The third quarter 10-Q further conveyed confidence to the market by stating that the FDA had not opted to convene an Advisory Committee for advice on the NDA. ¶ 30. The 2015 10-K filed on March 10, 2016 as well as the 10-Q filed on May 9, 2016, also reiterated all of the same misleading statements set forth above. ¶¶ 32, 36

On April 13, 2016, the Company presented at the 15th Annual Needham Healthcare Conference. Slide 16 of the presentation covered the number of dose titrations required for LPCN 1021 during the Phase 3 trial as compared to alternative competitor products. During that presentation, Defendant Patel made clear that his purpose was to "convince you to become part of Lipocine." To achieve that end, Defendant Patel described the upcoming PDUFA date on which the FDA's decision on the NDA was expected as a "huge value driving event" and also explained that competitors had run into problems with regard to approval so Lipocine is the "leader in the space." He went on to describe the "robust" safety and efficacy trial results without divulging that those results emanated from a different titration scheme than that submitted to the FDA for approval. Defendant Patel also identified "dosing" as one of the key differentiators between LPCN 1021 and competitor products. ¶ 34.

The Truth Emerges

On June 29, 2016, the Company issued a press releasing disclosing its receipt of a Complete Response Letter ("CRL") for LPCN 1021 from the FDA declining to approve LPCN 1021, which stated in relevant part:

> ***The CRL identified deficiencies related to the dosing algorithm for the label. Specifically, the proposed titration scheme for clinical practice was significantly different from the titration scheme used in the Phase 3***

trial leading to discordance in titration decisions between the Phase 3 trial and real-world clinical practice.

¶ 38. On this news, shares of Lipocine fell $3.17 per share or over 50% to close at $3.10 per share on June 29, 2016, damaging investors. ¶ 39.

ARGUMENT

I. Applicable Standards

When analyzing a complaint for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6), all factual allegations are taken as true and construed in the light most favorable to the non-moving party. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *See also Gee v. Pacheco*, 627 F.3d 1178, 1184 (10th Cir. 2010). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

To sustain a claim for securities fraud under Section 10(b), "a plaintiff must prove (1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Strougo v. Barclays PLC*, 105 F. Supp. 3d 330, 340-41 (S.D.N.Y. 2015) (citing *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157, 128 S. Ct. 761, 169 L. Ed. 2d 627 (2008)). Defendants here only challenge the first two elements, thus conceding that the Complaint satisfies the remaining four.

II. The Complaint Plausibly Alleges That Defendants Made Materially Misleading Statements

To state a valid Rule 10b–5 claim, a plaintiff must first plead that the defendant made an untrue or misleading statement of material fact or failed to state a material fact necessary to make a statement not misleading. *Adams v. Kinder-Morgan, Inc.*, 340 F.3d 1083, 1099-1100 (10th Cir. 2003). A plaintiff must "specify each statement alleged to have been misleading [and] the ... reasons why the statement is misleading...." 15 U.S.C. § 78u–4(b)(1). *See Adams,* 340 F.3d at 1095; *In re Zagg Sec. Litig.*, No. 12-cv-852, 2014 U.S. Dist. LEXIS 15783, at *11 (D. Utah Feb. 4, 2014). "A common-sense, case-by-case approach will edify any determination of whether the facts alleged are sufficient under this standard, requiring courts to determine whether, taken as a whole, the facts alleged support a reasonable belief that the defendant's statements identified by the plaintiff were false or misleading." *Corporate Stock Transfer, Inc. v. AE Biofuels, Inc.*, 663 F. Supp. 2d 1056, 1066 (D. Colo. 2009) (internal quotations and citation omitted); *Nova Leasing, LLC v. Sun River Energy, Inc.,* No. 11–cv–00689, 2012 U.S. Dist. LEXIS 44291 at *25 (D. Colo. Mar. 28, 2012).

Here, the Complaint "clearly sets out the allegedly misleading statements and the reasons why the statements are claimed to be misleading," which is all the Tenth Circuit requires. *Adams v. Kinder-Morgan, Inc.*, 340 F.3d 1083, 1096 (10th Cir. 2003). Specifically, the Complaint alleges that throughout the Class Period, Defendants issued detailed statements regarding the Phase 3 trial results for LPCN 1021 and the FDA approval process. Those statements included comprehensive detail regarding safety, efficacy, and the titration scheme used for the trial. The Complaint also alleges that these statements were materially misleading because they failed to inform investors that the Company sought FDA approval for LPCN 1021 using an *untested* titration scheme for which they did not have safety and efficacy data. This raised a substantial

risk that the FDA would decline to approve the NDA with the disparate titration scheme and require additional costly clinical testing causing further delay of the Company's prospects for generating product revenue.[2] Nothing more is required to adequately plead misleading statements. Defendants implicitly recognize the fallacy of their challenge given that they relegate a mere four pages of their twenty five page brief to addressing this element of the claim.

There can be little doubt that Lipocine's bait and switch on the FDA, whereby it put an entirely different titration scheme in the NDA from that tested during the Phase 3 trial, is precisely the kind of information "a reasonable investor would consider ... important in determining whether to buy or sell stock." *Grossman v. Novell, Inc.*, 120 F.3d 1112, 1119 (10th Cir. 1997). *See also In re Williams Sec. Litig.*, 339 F. Supp. 2d 1242, 1263 (N.D. Okla. 2003). This is particularly so given that the omitted information put the Company's primary chance of generating revenue from product sales at risk, or at minimum subject to delay. Indeed, the materiality of this information is readily established by the steep decline in Lipocine's stock price upon its revelation to the market. ¶ 39. *In re Merck & Co.*, No. 08-cv-2177 (DMC), 2009 U.S. Dist. LEXIS 78313, at *10 (D.N.J. Aug. 31, 2009) ("because Plaintiffs adequately allege that [the company's] stock price experienced significant drops 'immediately following' disclosure of the ENHANCE study test results, the Court finds it 'plausible on its face' that Defendants' misstatements and omissions relating thereto were indeed 'material.'").

The self-described basis for Defendants' threadbare challenge to this element of the claim is both a mischaracterization of the Complaint here and outright false. Defendants argue that, "Plaintiff identifies *no statement* where the Company opined on the likelihood of NDA approval

[2] Defendants' suggestion that the Complaint "summarily concludes" that the alleged statements were misleading, Def. Br. at 23, is simply false and completely disregards the detailed explanations provided in the Complaint for precisely why Defendants' statements were misleading. *See, e.g.*, ¶ 21.

based on Phase 3 results, or in any way touted or even referenced the titration schemes." Def. Br. at 20-21. First, this is not, and never has been, a case about a company that guaranteed approval of its drug product. Rather it is a case about a company and its executives who described a titration scheme used during the LPCN 1021 Phase 3 clinical trial for which they reported positive safety and efficacy results, but failed to divulge that the NDA requested approval of the drug using a completely different *and untested* titration scheme. This put the NDA at risk and should have been explained to investors.

Second, Defendants contention that the Complaint does not identify a statement where the Company referenced titration is as puzzling as it is false.[3] *See, e.g.*, ¶ 20 ("All subjects randomized to LPCN 1021 were started at 225 mg testosterone undecanoate ("TU") (equivalent to ~ 142 mg of testosterone) twice daily ("BID") ***and then dose titrated***, if needed, up to 300 mg TU BID or down to 150 mg TU BID. ***Dose titration decisions*** were based on serum testosterone levels measured during weeks 3 and 7."); ¶ 26 ("In addition, 85% of the subjects reached their final dose with no more than one dose titration."); ¶¶ 22, 30, 32, 34, 36.

A. Defendants' Held a Clear Duty to Disclose its Bait and Switch on the FDA

Indeed, the multitude of, not only references to, but detailed descriptions of the titration scheme, as well as fulsome descriptions of the safety and efficacy data and the FDA approval process, triggered a clear duty for Defendants to disclose that they placed the LPCN 1021 NDA at risk of non-approval by replacing the titration scheme with one that had not been vetted with the FDA or clinically tested. *Karacand v. Edwards*, 53 F. Supp. 2d 1236, 1243-44 (D. Utah 1999) (duty to disclose what was "needed so that what was revealed would not be so incomplete as to mislead.") (internal quotations and citation omitted). Defendants' citation to *McDonald v.*

[3] Defendants repeat this falsity again on page 22 of their brief. ("Defendants made no disclosures about the titration schemes used in Phase 3…")

Kinder-Morgan, Inc. is therefore unavailing. Def. Br. at 21. There, the court held that Defendants did not have a duty to disclose the allegedly omitted information because it was both "immaterial" and "[did] not alter the meaning of the statements set out in 10-Q." *McDonald v. Kinder-Morgan, Inc.*, 287 F.3d 992, 998 (10th Cir. 2002). Such is not the case here. The fact that Defendants replaced the titration scheme in the NDA with an untested one was clearly material given that it jeopardized the NDA, a fact of particular significance given that Lipocine has no approved drugs on the market and no other imminently looming prospects for approval. Moreover, given that this omitted fact would have directly altered investors' understanding of the import of the Phase 3 trial results and the prospects of success for the LPCN 1021 FDA approval process described in Class Period filings, this case bears no resemblance *McDonald.*

Further, Defendants' claim that because the contents of unapproved NDAs are typically "closely guarded" that somehow absolves them from failing to tell the market that it used a different titration scheme in the NDA than it tested during the Phase 3 trial. Given that the Company chose to speak about titration in its Class Period statements, and even publicly described the titration scheme it used during Phase 3, it is simply implausible to suggest that the subject became a "highly confidential trade secret" when Defendants inexplicably submitted the LPCN 1021 NDA with a completely different titration scheme.

III. The Complaint Adequately Pleads A Strong Inference of Scienter

At the pleading stage, a plaintiff alleging fraud in a § 10(b) action must only plead facts rendering an inference of scienter at least as likely as any plausible opposing inference. *Tellabs,* 551 U.S. at 314. "The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the smoking-gun genre, or even the most plausible of competing inferences." *Id.* at 324. (internal quotations and citation omitted). Indeed, "[f]aced with two seemingly equally strong inferences, one favoring the plaintiff and one favoring the defendant, it is inappropriate" for a

court to "make a determination as to which inference will ultimately prevail" because that would "invade the traditional role of the factfinder." *Pirraglia v. Novell, Inc.,* 339 F.3d 1182, 1188 (10th Cir. 2003).

The court must review ***all*** allegations ***holistically***. *Matrixx Initiatives, Inc. v. Siracusano,* 563 U.S. 27, 48 (2011); *Slayton v. Am. Express Co.*, 604 F.3d 758, 775 (2d Cir. 2010) (court must consider "the whole factual picture painted by the Complaint" and not "the presence or absence of certain types of allegations") (quotation omitted). Defendants "cannot secure dismissal by cherry-picking only those allegations susceptible to rebuttal and disregarding the remainder." *In re Philip Services Corp. Sec. Litig.*, 383 F. Supp. 2d 463, 476 (S.D.N.Y. 2004).

A. The Complaint Adequately Alleges Defendants' Recklessness

In the Tenth Circuit, proof of recklessness is sufficient to establish scienter. *See Weinstein v. McClendon*, 757 F.3d 1110, 1114 (10th Cir. 2014). "[T]o survive dismissal, plaintiffs must ***minimally*** allege that the defendants' conduct falls within the definition for recklessness." *In re Veeco Instruments, Inc. Sec. Litig.*, 235 F.R.D. 220, 231 (S.D.N.Y. 2006) (emphasis added) (quoting *In re Winstar Commc'ns*, No. 01-cv-3014 (GBD), 2006 U.S. Dist. LEXIS 7618, at *21 (S.D.N.Y. Feb. 24, 2006)). "[A] defendant acts recklessly when his or her conduct amounts to an extreme departure from the standards of ordinary care, and presents a danger of misleading buyers or sellers which is either known to the defendant or is so obvious that the defendant must have been aware of the danger." *Zagg*, 2014 U.S. Dist. LEXIS 15783 at *14 (citing *City of Phila. v. Fleming Cos., Inc.*, 264 F.3d 1245, 1260 (10th Cir. 2001)).

The Complaint is replete with facts that, when considered holistically, give rise to a strong and compelling inference that the Defendants acted with knowledge, or at a minimum, acted recklessly. Important to note is that Defendants' beliefs as to the chances the FDA would approve the LPCN 1021 NDA are not relevant; what is relevant is that Defendants knew about

and failed to disclose that the replacement of the titration scheme created a heightened risk of rejection. Perhaps most significantly, there is no dispute that Defendants had full awareness of the contents of the alleged misleading statements and had contemporaneous full awareness that the titration scheme used in Phase 3 was not the titration scheme included in the LPCN 1021 NDA. The fact that Defendants changed the titration scheme strongly suggests that there was something terribly amiss with the scheme used for the Phase 3 trial. There is no other logical explanation for why Defendants would put an entirely new untested titration scheme into the NDA that had not been previously vetted with the FDA, unless the first titration scheme had deleterious deficiencies. Nevertheless, Defendants hid the change from investors. Moreover, it is simply implausible that Defendants did not know (or at minimum were reckless in not knowing) that if they were to change something so fundamental as a dosing algorithm/titration scheme for a drug ***after*** it had been fully tested in a clinical trial, that created a risk that the FDA would reject the NDA and require additional testing. How much of a drug a patient must take to achieve optimal results without incurring harmful side effects has a direct bearing on efficacy and safety. Yet, the only safety and efficacy results provided to the public and submitted to the FDA related to a titration scheme that the Company inexplicably decided to "scrap." Defendants' decision to hide their "bait and switch" from investors therefore equates to clear recklessness. *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008) *aff'd sub nom. State Universities Ret. Sys. of Illinois v. Astrazeneca PLC*, 334 F. Appx. 404 (2d Cir. 2009) ("if the management knows that certain facts will necessarily prevent the regulatory approval or the marketing of the drug and conceals these facts from the investing public, then there is scienter."), cited favorably in *In re Delcath Sys. Sec. Litig.*, 36 F. Supp. 3d 320, (S.D.N.Y. 2014).

To the extent any doubt remains as to Defendants' full awareness of development activities relating to LPCN 1021 and the contents of the NDA, this Court need only adopt a common sense approach when viewing the relevant facts holistically, as set forth below, in accordance with *Tellabs*:

Fact- Lipocine is a one trick pony. It has never had a FDA approved drug on the market. The only other two products in its arsenal lag far behind LPCN 1021 in the regulatory approval process. There is thus a powerful inference that the CEO and CFO of Lipocine had complete knowledge of all facts relevant to the development of LPCN 1021 and the regulatory approval process. *See Stone v. Life Partners Holdings, Inc*., 26 F. Supp. 3d 575, 600 (W.D. Tex. 2014)("Furthermore, when a company is a single-product company, like Life Partners, the gravity of misrepresentations about the product to the public is strong evidence that the 'danger was either known to the defendant or so obvious that the defendant must have been aware of it.'"). Before making a significant change in the NDA that rendered it inconsistent with the Phase 3 trial, the leaders of a company with no marketable products and only one drug up for approval, would have undoubtedly educated themselves as to the consequences of making such a change. They would have known that putting an untested titration scheme into the NDA with no related clinical data, would raise a material risk that the FDA could reject the application. Following *Tellabs*, courts across a multitude of circuits have upheld a strong inference of scienter where the fraud involved a company's core operations—as is the case here. The Second, Third, Seventh, and Ninth Circuits have recognized that allegations of fraud arising from a company's core operations can support an inference of scienter.[4] As the Seventh Circuit reasoned

[4] In *South Ferry LP v. Killinger*, the Ninth Circuit concluded that "[a]llegations that rely on the core-operations inference are among the allegations that may be considered in the complete PSLRA analysis." 542 F.3d 776, 784 (9th Cir. 2008). The Third Circuit in *Institutional Investors Group v. Avaya, Inc*., referring to the "core business inference," 564 F.3d 242, 268 (3d Cir.

in *Makor Issues & Rights, Ltd. v. Tellabs Inc., ("Tellabs II")*, it would be "exceedingly unlikely" for a CEO to be unaware of problems affecting the company's major products. 513 F.3d 702, 711 (7th Cir. 2008). *See also Hoi Ming Michael Ho v. Duoyuan Global Water, Inc.*, 887 F. Supp. 2d 547, 575 (S.D.N.Y. 2012) ("Knowledge of the falsity of a company's financial statements can be imputed to key officers who should have known of facts relating to the core operations of their company...")

Fact- throughout the Class Period, Lipocine only had between 17-25 employees according to its SEC filings. Only half of those employees had any involvement in drug development activities. LPCN 1021 has been the primary drug under development at all relevant times. It is well understood that the smaller a company is, the less plausible it is that the CEO and CFO would not have full awareness of all development activities relating to its key product and only potential source of product revenue in the imminent future.

Fact- Defendants Patel and Brown put themselves forth as knowledgeable about the details of the Phase 3 trial for LPCN 1021 and the regulatory approval process, which further strengthens the inference of scienter. *See, e.g., KB Partners I, L.P. v. Barbier,* 907 F. Supp. 2d 826, 831-32 (W.D. Tex. 2012). They did so by making statements in Class Period SEC filings on those subjects. Moreover, Defendant Patel presented at the 15th Annual Needham Healthcare Conference where he spoke in detail about the LPCN 1021 Phase 3 trial, including the subject of titration and LPCN 1021's future prospects.

2009), specifically recognized that the "perceived importance of margins supports an inference that [Avaya's CFO] was paying close attention to these numbers." *Id.* at 271. *See also New Orleans Emps. Ret. Sys. v. Celestica, Inc.*, 455 F. Appx. 10, 14 n.3 (2d Cir. 2011) (allegations of a company's core operations, "can provide supplemental support for allegations of scienter, even if they cannot establish scienter independently. That view finds support in decisions by this court and district courts within this circuit.").

Fact- at all relevant times, Defendants Patel and Brown stood at the helm of Lipocine. Defendants had access to information and, as senior executives and signatories and/or authors of the Company's SEC filings and press releases, had a duty to inquire and investigate, familiarize and reassure themselves as to the truth of their statements. *See In re Refco, Inc. Sec. Litig.*, 503 F. Supp. 2d 611, 649 (S.D.N.Y. 2007); *see also In re Atlas Air Worldwide Holdings, Inc.,* 324 F. Supp. 2d 474, 496 (S.D.N.Y 2004) (same). Their failure to do so amounts to recklessness. For this reason, the Court can presume that the CEO and CFO of Lipocine knew that the LPCN 1021 NDA contained an untested titration scheme that had not been utilized during the Phase 3 trial, whose results were touted throughout the Class Period. Indeed, an allegation of "falsity may itself be indicative of scienter where it is combined with allegations regarding a management's role in the company that are particular and suggest that the defendant had actual access to the disputed information, and where the nature of the relevant fact is of such prominence that it would be absurd to suggest that management was without knowledge of the matter." *Zucco Partners, LLC v. Digimarc Corp.,* 552 F.3d 981, 1000 (9th Cir. 2009) (internal quotations omitted); s*ee also Scott v. ZST Digital Networks, Inc.,* 896 F. Supp. 2d 877, 892 (C.D. Cal 2012).

In addition to the above referenced facts, Defendants Patel and Brown's intimate involvement in the development activity surrounding LPCN 1021—rendering it likely that they had full awareness of the risks inherent in changing an element as fundamental as dosing/titration in the NDA-- is also corroborated by the statements of two confidential witnesses. Courts in this Circuit have found that allegations from confidential witnesses can support a finding of scienter. *See, e.g., Better v. YRC Worldwide In*c., No. 11-cv-2072, 2012 U.S. Dist LEXIS 136749, at *10-11 (D. Kan. Sept. 25, 2012) (court considered confidential witness accounts which corroborated defendants' knowledge or reckless disregard of concealed facts); *In re SemGroup Energy*

Partners, L.P. Sec. Litig., 729 F. Supp. 2d 1276, 1290 n.1 (N.D. Okla. 2010); *Mishkin v. Zynex Inc.,* 2011 U.S. Dist. LEXIS 34467, at *7 (D. Colo. 2011). A court should give weight to statements of a confidential witness where those statements are supported by detail "regarding the basis of the informant's knowledge and the knowledge itself." *In re Thornburg Mortg., Inc. Sec. Litig.,* 824 F. Supp. 2d 1214, 1226 n.11 (D.N.M. 2011). This is especially true where confidential witnesses corroborate each other. *See In re Daou Sys. Inc. Sec. Litig.*, 411 F.3d 1006, 1015 (9th Cir. 2005)*; In re Cabletron Sys., Inc.*, 311 F.3d 11, 29 (1st Cir. 2002). Here, the Complaint identifies the confidential witnesses, specifies each witness's affiliation with Lipocine, title, position, geographic area of employment, length of employment, and job responsibilities, all of which establish the basis of their knowledge. *See, e.g.*, ¶¶ 17-19. Accordingly, "the allegations based on the statements of the CWs are entitled to significant weight because the complaint describes the bases of the CWs' knowledge, the positions they held, their exposure to the relevant conduct, and the relevant time frame." *Mishkin,* , 2011 U.S. Dist. LEXIS 34467, at *19.

Defendants rely heavily on the *Fleming* and *Zagg* cases while attacking cherry picked allegations regarding their positions in Lipocine and their roles as signatories on the SEC filings. Aside from ignoring *Tellabs'* directive to conduct a holistic analysis, Defendants ignore that both cases are factually distinguishable. In *Fleming,* the company disclosed its exposure to litigation arising from its cost-plus sales practices, including the potential for large losses, but not a specific lawsuit which resulted in a $50 million verdict. *Fleming*, 264 F.3d at 1264-65. In concluding that scienter was not sufficiently pled, the *Fleming* court focused on the relatively small size of potential damages from the lawsuit as compared to total assets, which is in stark contrast to Lipocine where the entire Company's fortunes depend upon FDA approval of one

product. *Id.* In *Zagg,* the defendant CEO failed to disclose in Company's filings that his holdings of Zagg stock were leveraged and subject to a margin call. *Swabb v. Zagg, Inc. (In re Zagg Sec. Litig.)*, 797 F.3d 1194, 1203-04 (10th Cir. 2015). The court found there was no scienter because the market was otherwise alerted by the CEO's personal Form 144 filings and though the CEO had violated certain SEC regulations, those violations alone did not suffice to create an inference of scienter. *Id.*

Here, given the factors described above, a reasonable person would deem the inference of Defendants' scienter cogent and "at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs,* 551 U.S. at 324.

B. Lipocine's Risk Disclosures Do Not Insulate Defendants from Liability

Defendants next argue that their false and misleading statements are immunized by risk disclosures in Lipocine's SEC filings. Def. Br. at 17-18. Defendants' reliance on "risk disclosures" in Lipocine's SEC filings should be rejected because by affirmatively and repeatedly speaking about the LPCN 1021 Phase 3 trial (including the subject of titration) and the FDA regulatory approval process, Defendants had a duty to disclose the full truth about the Company's decision to substitute a different titration scheme in the NDA that had not been tested, therefore raising the risk the drug would not receive approval. The cautionary language in Lipocine's SEC filings consisted only of general warnings about the risks inherent to the FDA approval process for any drug. Defendants' failure to disclose the specific risk, of which they were aware, that the FDA could decline their application because they chose to switch titration schemes without the necessary additional testing, rendered their statements misleading. Misrepresenting reality as a mere risk is deceptive: "to warn that the untoward may occur when the event is contingent is prudent, to caution that it is only possible for the unfavorable events to

happen when they have already occurred is deceit." *FindWhat Investor Grp. v. FindWhat.com,* 658 F.3d 1282, 1299 (11th Cir. 2011) (internal quotations and citation omitted).

Defendants' claim that they adequately warned investors regarding the "risks surrounding FDA approval" is simply unavailing. In *Amylin I*, defendant similarly, and unsuccessfully, claimed that cautionary language regarding the risks and uncertainties of the drug development process was meaningful. *In re Amylin Pharms., Inc. Secs. Litig.*, 2002 U.S. Dist. LEXIS 19481 (S.D. Cal. Oct. 10, 2002). However, as the *Amylin I* court held, "Individuals commonly ignore such boilerplate warnings. Even if investors read them, merely warning investors that FDA may not approve the drug tells them something they already know." *Id.* at *26-*27; *see also Irvine v. ImClone Sys., Inc.*, 02 CIV.109 RO, 2003 U.S. Dist. LEXIS 9342, at *4 (S.D.N.Y. June 4, 2003); *In re Sepracor, Inc. Sec. Litig.*, 308 F. Supp. 2d 20, 34 (D. Mass. 2004).

Here, Defendants issued a boilerplate litany of generally applicable risk factors regarding potential FDA approval, none of which identified the specific fact posing risks to the approval of LPCN 1021. Such nonspecific warnings, especially when Defendants were aware of specific risks, do not afford them any protection. *See Rombach v. Chang*, 355 F.3d 164, 173 (2d Cir. 2004) ("Cautionary words about future risk cannot insulate from liability the failure to disclose that the risk has transpired.").

Finally, the dramatic drop in the price of Lipocine's stock following the corrective disclosure further undermines Defendants' claim that investors were adequately warned regarding the risks to approval, as investors were obviously shocked to learn that the NDA included a substitute untested titration scheme that led the FDA to issue a CRL. *Lapin v. Goldman Sachs Group, Inc.*, 506 F. Supp. 2d 221, 236 (S.D.N.Y. 2006) ("Goldman stock still suffered a sizable drop in value when the state and federal investigations into investment bank

practices were announced to the investing public, thereby suggesting that the news reports and Stefansky complaint did not put Plaintiff on inquiry notice."); *In re Vivendi Universal, S.A. Sec. Litig.*, 381 F. Supp. 2d 158, 182 (S.D.N.Y. 2003) (same).

C. The Complaint Identifies Defendants' Motive

Lipocine had no products on the market and therefore no means of earning revenue to keep its operations running and fund its development activities aside from generating outside capital. Indeed, during the Class Period, the Company completed an underwritten public offering which raised net proceeds of approximately $32.4 million. ¶ 24. To convince investors to participate in the offering, the Company had to portray the prospects for LPCN 1021 as positive. The very same day the Company completed its offering, it issued a press release, which discussed titration, efficacy, and safety in detail—and also suggested that the Company would not have to conduct additional clinical testing to achieve approval. Telling the market that Defendants had shoe horned a new titration scheme into the NDA, suggesting there were glaring issues with the tested scheme, would have stymied the Company's ability to raise the funds it needed. Indeed, the issues with the titration schemes must have been so severe that the FDA told Lipocine that the only path to approval after the CRL involved conducting new trials using only fixed dosing and no titration scheme at all. *See* Declaration of Joni Jacobsen, filed on June 12, 2017, Doc No. 50 ("Jacobsen Decl."), Ex. G, at 7.

Defendants argue that the inference of scienter is not plausible given their work with the FDA in designing clinical testing protocols, and the amount of money they spent on the Phase 3 trial. Def. Br. at 17. This argument focuses on whether Defendants had a plausible motive to commit securities fraud, which, as noted above, the Tenth Circuit does not require. Regardless, the fact that Defendants designed testing protocols with the FDA (which included a titration scheme that they replaced before submitting the NDA) and spent money on a clinical trial does

not negate scienter. All the conversations with the FDA had already taken place and the money for the Phase 3 trial already spent when Defendants made the decision to replace the titration scheme for the NDA submission. Additionally, Defendants argument assumes that decisions to commit fraud are always rational. Companies often "gamble" when making business decisions, such as the one the Defendants made here to submit the LPCN 1021 NDA with a different titration scheme. While entitled to risk that the FDA would ignore the grave deficiencies in the NDA, Defendants were not at liberty to hide their gamble from investors. As the court noted in *In re Amylin Pharms., Inc. Secs. Litig.*, No. 01cv1455 BTM (NLS), 2003 U.S. Dist. LEXIS 7667, at *13 (S.D. Cal. May 1, 2003):

> There is nothing unlawful about taking a calculated risk. However, if, as Plaintiffs allege, Defendants misled Plaintiffs about such risks by making assurances regarding the completeness of the data and the likelihood of FDA approval, Defendants may be held liable.

See also Alaska Elec. Pension Fund v. Flowserve Corp., 572 F.3d 221, 231-32 (5th Cir. 2009) (holding that while a Company is "free to be wrong" in its public statements, it is not free to commit fraud).

IV. The Control Person Allegations are Adequately Pled

Defendants contest Plaintiff's Section 20(a) claims only on the basis that the underlying Section 10(b) claim should be dismissed. Defs. Br. at 24. Because those arguments fail, the Court should sustain Plaintiff's claims under Section 20(a) of the Exchange Act.

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss should be denied in full.[5]

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Respectfully submitted,

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[5] In the event that all or any portion of the Complaint is dismissed, Plaintiff respectfully seeks leave to amend under Fed. R. Civ. P. 15.